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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/944,850	10/06/1997	DAVID R. WALT	TU-97-01	1980

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EXAMINER

HANNAHER, CONSTANTINE

ART UNIT

PAPER NUMBER

2878

DATE MAILED: 06/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	08/944,850	WALT ET AL.
	Examiner	Art Unit
	Constantine Hannaher	2878

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 20 May 2002.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.
- 4) Claim(s) 39-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 39-48 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |  |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                               | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)           | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ .                                   |

## **DETAILED ACTION**

### **Continued Examination Under 37 CFR 1.114**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 20, 2002 has been entered.

### **Information Disclosure Statement**

2. No copy of WO0048000A1 is found, nor any correction to any information disclosure statement. The transmittal of the request for continued examination does not suggest that any such submission was made.

### **Claim Rejections - 35 USC § 102**

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. Claims 39, 40, 43-45, 47, and 48 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Pinkel *et al.* (US005690894A).

With respect to independent claim 39, Pinkel *et al.* discloses an assay method corresponding to the disclosed apparatus (Fig. 4) which comprises a sensor array **14** having at least two subpopulations (the groups of strands **10**) of different sensor elements (sensor ends **11**, where each group may have a different sensor, column 8, lines 50-67). The assay method would comprise the steps of providing the sensor array **14**, adding a sample **30** comprising a first target analyte that binds to the first sensor elements (*e.g.*, first collection **25**), measuring a first fluorescence signal of a first of the first sensor elements **11** and a second fluorescent signal of a second of the first sensor elements **11** (column 13, lines 33-39) with detector **20**, and summing the first fluorescence signals (column 9, lines 12-14 and 21-25).

With respect to dependent claim 40, the method suggested by Pinkel *et al.* further comprises adding a sample **30** comprising a second target analyte that binds to the second sensor elements (*e.g.*, second collection **26**), measuring a third fluorescence signal of a first of the second sensor elements **11** and a fourth fluorescent signal of a second of the second sensor elements **11** (column 13, lines 33-39) with detector **20**, and summing the second fluorescence signals (column 9, lines 12-14 and 21-25).

With respect to dependent claim 43, the sensor elements (ends **11**) in the method of Pinkel *et al.* comprise chemical functional groups (column 10, lines 28-34).

With respect to dependent claim 44, the sensor elements (ends **11**) in the method of Pinkel *et al.* may comprise oligonucleotides in view of column 10, lines 56-63 and column 3, line 13.

With respect to dependent claim 45, the first target analyte in the method of Pinkel *et al.* is an oligonucleotide (column 4, line 65 to column 5, line 1).

With respect to dependent claim 47, the increase in signal-to-noise ratio using the method of Pinkel *et al.* is inherent in (necessarily follows from) the identity of the apparatus and method of operation.

With respect to dependent claim 48, the sensor array **14** provided in the method of Pinkel *et al.* comprises a fiber optic bundle.

### **Claim Rejections - 35 USC § 103**

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pinkel *et al.* (US005690894A).

With respect to dependent claim 46, it would have been obvious to one of ordinary skill in the art at the time the invention was made to adjust the baseline of fluorescence signals in the method of Pinkel *et al.* because the detector system may be employed with a computerized data acquisition system and analytical program (column 12, lines 10-22) and such an adjustment (calibration) is a known and useful step in accurately measuring responses.

7. Claims 41 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pinkel *et al.* (US005690894A) in view of Lough *et al.* (US005900481A).

With respect to dependent claim 41, the sensor elements in the method of Pinkel *et al.* do not comprise beads, but are instead the ends **11** of the fiber strands **10** which may have a specific shape (column 7, line 56 to column 8, line 3). Lough *et al.* shows that beads are known (Fig. 1) as

elements in a sensor array (column 5, lines 62-67). The beads of Lough *et al.* are suitable for the types of binding molecules used and fluorescent signals measured in the sensor array **14** of Pinkel *et al.* and further provide the convex surface Pinkel *et al.* identifies as advantageous. Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Pinkel *et al.* to specify that the sensor ends **11** therein were bound to beads as suggested by Lough *et al.* (as the fiber strands **10** in Pinkel *et al.* qualify as a support as described by Lough *et al.* at column 3, line 29).

With respect to dependent claim 42, the sensor elements in the method of Pinkel *et al.* do not comprise beads, but are instead the ends **11** of the fiber strands **10** which may have a specific shape (column 7, line 56 to column 8, line 3). Lough *et al.* shows that beads are known (Fig. 1) as elements in a sensor array (column 5, lines 62-67). The beads of Lough *et al.* are suitable for the types of binding molecules used and fluorescent signals measured in the sensor array **14** of Pinkel *et al.* and further provide the convex surface Pinkel *et al.* identifies as advantageous. Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Pinkel *et al.* to specify that the sensor ends **11** therein were bound to beads as suggested by Lough *et al.* (as the fiber strands **10** in Pinkel *et al.* qualify as a support as described by Lough *et al.* at column 3, line 29). The connection of the beads suggested by Lough *et al.* and the sensor ends **11** in the sensor array **14** provided in the method suggested by Pinkel *et al.* is a choice within the ordinary skill in the art at the time the invention was made. The specification of "wells" would have been obvious in view of the mechanical advantage afforded thereby in retaining the suggested beads to the faces of the fiber optic strands **10** and the knowledge from Lough *et al.* at column 3, lines 35-37 that beads in pits (functionally equivalent to the recited wells) are known.

### Response to Submission(s)

8. The papers filed on May 20, 2002 (certificate of mailing dated May 6, 2002) have not been made part of the permanent records of the United States Patent and Trademark Office (Office) for this application (37 CFR 1.52(a)) because of damage from the United States Postal Service irradiation process. The above-identified papers, however, were not so damaged as to preclude the USPTO from making a legible copy of such papers. Therefore, the Office has made a copy of these papers, substituted them for the originals in the file, and stamped that copy:

**COPY OF PAPERS  
ORIGINALLY FILED**

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If applicant wants to review the accuracy of the Office's copy of such papers, applicant may either inspect the application (37 CFR 1.14(d)) or may request a copy of the Office's records of such papers (*i.e.*, a copy of the copy made by the Office) from the Office of Public Records for the fee specified in 37 CFR 1.19(b)(4). Please do **not** call the Technology Center's Customer Service Center to inquiry about the completeness or accuracy of Office's copy of the above-identified papers, as the Technology Center's Customer Service Center will **not** be able to provide this service.

If applicant does not consider the Office's copy of such papers to be accurate, applicant must provide a copy of the above-identified papers (except for any U.S. or foreign patent documents submitted with the above-identified papers) with a statement that such copy is a complete and accurate copy of the originally submitted documents. If applicant provides such a copy of the above-identified papers and statement within **THREE MONTHS** of the mail date of this Office action, the Office will add the original mailroom date and use the copy provided by applicant as the permanent Office record of the above-identified papers in place of the copy made by the Office. Otherwise, the Office's copy will be used as the permanent Office record of the above-identified papers (*i.e.*, the Office will use the copy of the above-identified papers made by the Office for examination and all other purposes). This three-month period is not extendable.

9. Applicant's arguments filed May 20, 2002 have been fully considered but they are not persuasive.

The contention that "a" phototube detecting "a" signal from "a" group of optical fibers bearing the same species of biological binding partner does not constitute a summation (*i.e.*, an addition of the signal from one fiber in the group to the signal of another fiber in the group) is not

persuasive, or requires a much narrower definition of "summing" than is required for the scope of sole independent claim 39.

The first argument regarding the rejections under 35 U.S.C. 103(a) is bizarre. It is *entirely legitimate* for an Examiner to reject a claim for nonobviousness when the parent claim has been rejected for anticipation. There is no logical or legal impossibility, since it long established that "anticipation is the epitome of obviousness," *In re Fracalossi and Wajer*, 681 F.2d 792, 215 USPQ 569 (CCPA 1982).

Pinkel *et al.* does not require modification with regard to claim 46, only the recognition by those skilled in the art that calibration is an ordinary element of a computerized data acquisition system and analytical program.

In response to applicant's argument that the beads of Lough *et al.* would not attach to the fibers of Pinkel *et al.*, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Pinkel *et al.* seeks increased efficiency for the biosensor by an increase in surface area, as by the use of a concave or convex sensor end. It would have been apparent to one skilled in the art that a bead as described by Lough *et al.* provides the ultimate in convexity, and the increased efficiency in the greater surface area provided by a bead would have been entirely sufficient as motivation.

For at least the reasons explained above, Applicant is not entitled to a favorable determination of patentability in view of the arguments submitted May 20, 2002.

### **Conclusion**

10. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Constantine Hannaher whose telephone number is (703) 308-4850. The examiner can normally be reached on Monday-Friday with flexible hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frank G. Font can be reached on (703) 308-4881. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9318 for regular communications and (703) 872-9319 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0956.

ch  
June 17, 2002



Constantine Hannaher  
Primary Examiner